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(54) **ADJUSTABLE LENGTH REAR TIP
EXTENDER FOR PENILE PROSTHESIS**

(75) Inventors: **Harshad M. Borgaonkar**, Blaine, MN
(US); **Randall H. Zauner**, Stillwater,
MN (US); **Christopher A. Wilhoit**,
Minneapolis, MN (US)

(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple
Grove, MN (US)

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USPC 600/38-41
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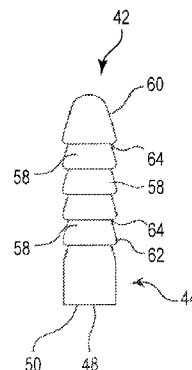
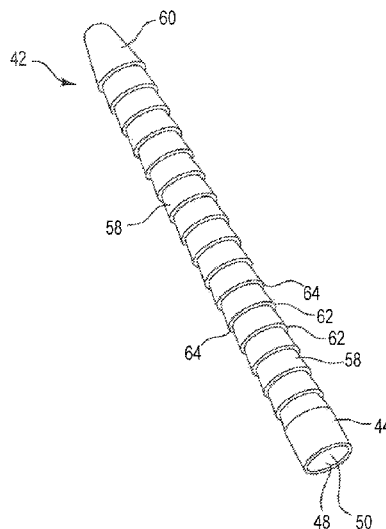
Primary Examiner — Samuel Gilbert

(74) *Attorney, Agent, or Firm* — Brake Hughes
Bellermann LLP

(57) **ABSTRACT**

An implantable penile prosthesis having an adjustable length
rear tip extender. The extender is connectable with at least
one inflatable cylinder. The adjustable length rear tip
extender can be telescoping, or include one or more seg-
ments capable of being cut away or otherwise removed, to
adjust the effective length for the at least one inflatable
cylinder.

9 Claims, 4 Drawing Sheets



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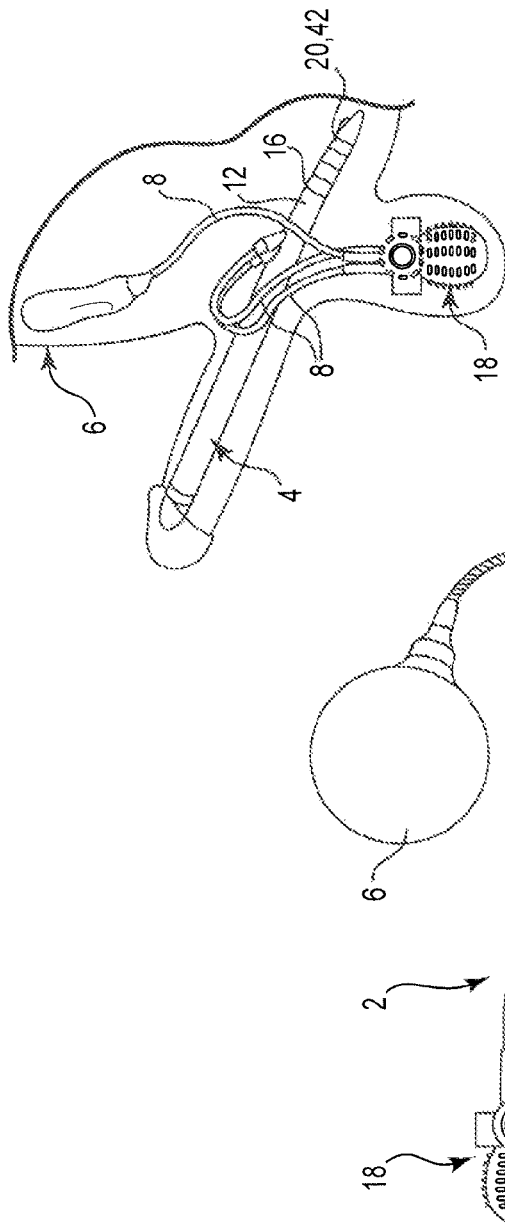


Fig. 1

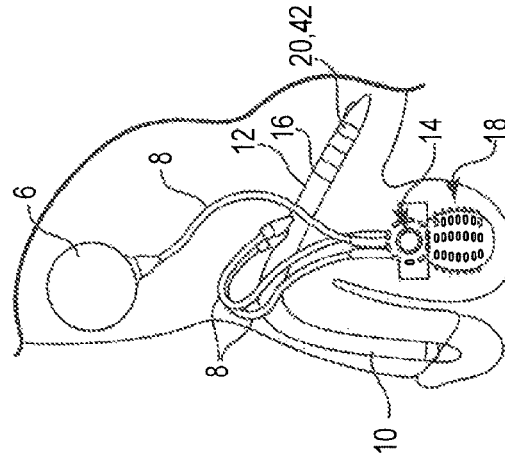


Fig. 2

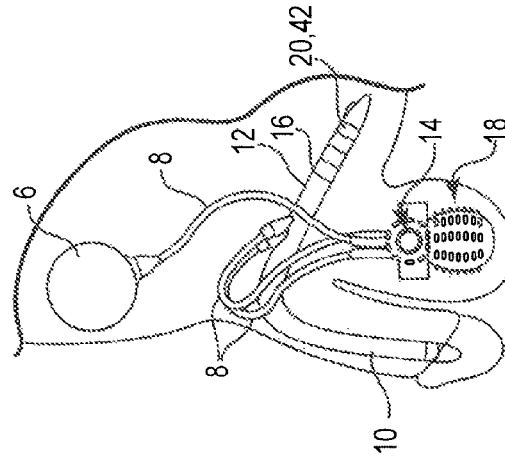


Fig. 3

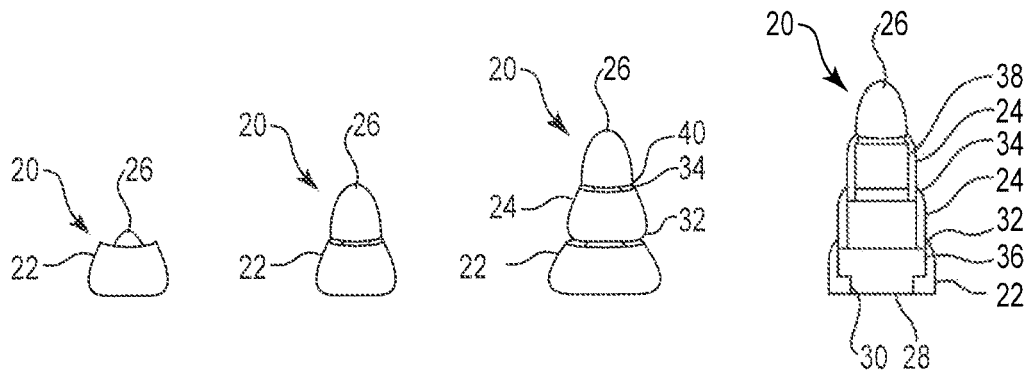


Fig. 4a

Fig. 4b

Fig. 4c

Fig. 4d

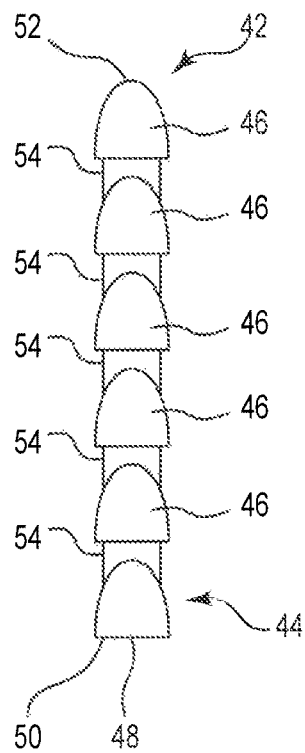


Fig. 5

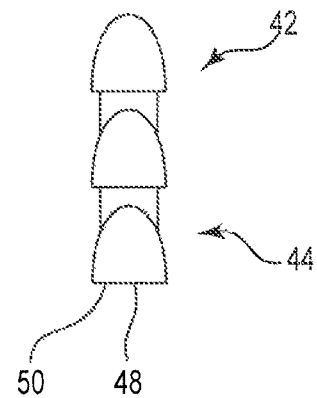


Fig. 6

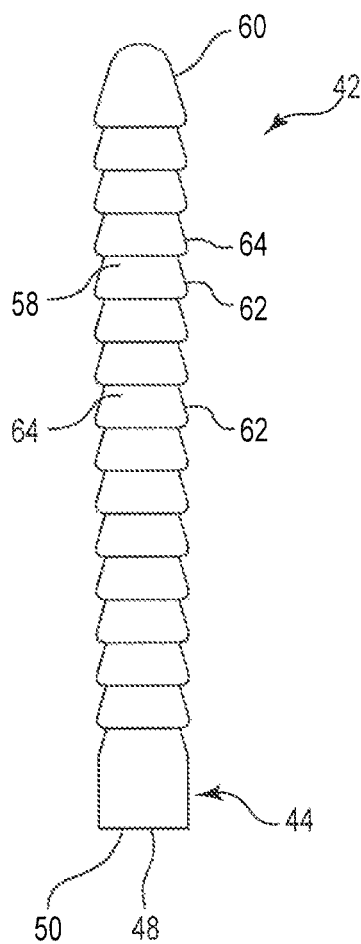


Fig. 7

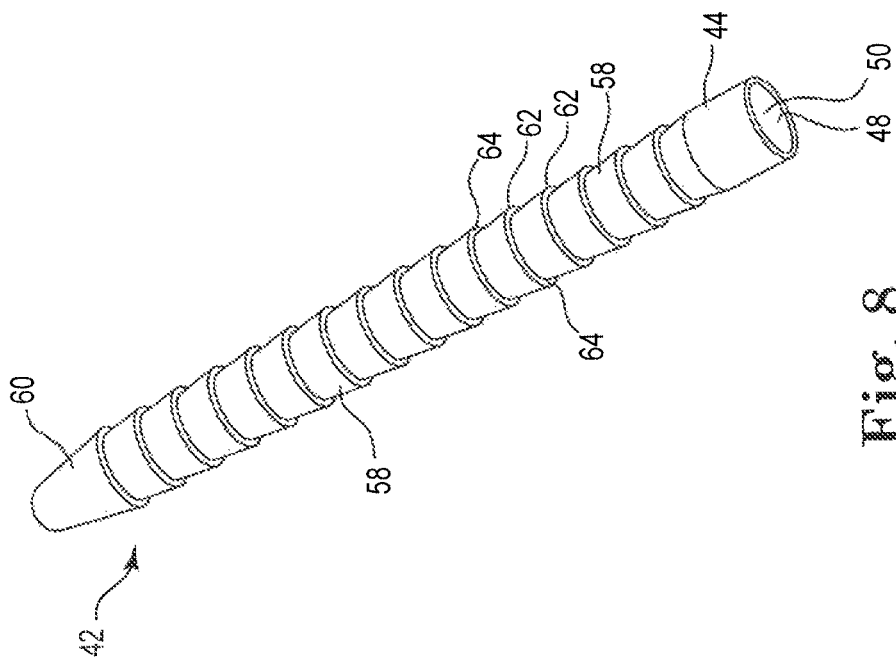


Fig. 8

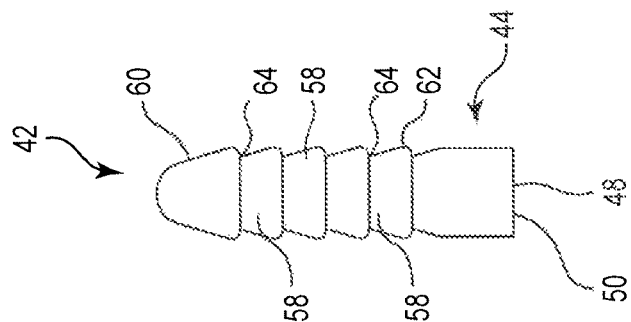


Fig. 9

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ADJUSTABLE LENGTH REAR TIP EXTENDER FOR PENILE PROSTHESIS

PRIORITY

This application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/425,395, filed Dec. 21, 2010, which is incorporated herein by reference in its entirety.

FIELD OF THE DISCLOSURE

The present invention is generally directed to an implantable penile prosthesis and, more specifically, to an inflatable cylinder to which a rear tip extender can be affixed, wherein the rear tip extender provides an adjustable effective length for the inflatable cylinder.

BACKGROUND OF THE DISCLOSURE

Erectile dysfunction is a psychological or physical disorder preventing males from forming or maintaining an erection during sexual intercourse. Erectile dysfunction is treatable through the implantation of a selectively inflatable penile prosthesis within the corpus cavernosum of the penis that mechanically erects the penis. Typically, an implantable penile prosthesis comprises at least one inflatable cylinder positioned within the corpus cavernosum and operably linked to an apparatus for selectively inflating the cylinder. Generally, a first and second inflatable cylinder is placed within the corpus cavernosum. A rear tip extender, as disclosed in U.S. Pat. No. 6,808,489 to George et al., which is incorporated by reference in its entirety, can be fitted to the rear tip of each inflatable cylinder to change the effective length of the inflatable cylinder according to the needs of the patient. A rear tip extender is often necessary to insure the implantable penile prosthesis is properly fitted and positioned within the penis according to the specific anatomy of the male patient.

Rear tip extenders typically comprise a molded polymer and, as a result, cannot be inflated or changed in size. As a result, implantable penile prosthesis are often provided with a plurality of rear tip extenders having a range of sizes from which a surgeon can select the appropriate size that best suits the patient's needs. The unused rear tip extenders are often discarded, creating a considerable amount of waste. While the unused rear tip extenders are often returned to the manufacturer, manufacturers are left with large inventories of rarely used "off-sizes" of rear tip extenders that are ultimately discarded. Similarly, as each rear tip extender is individually molded, each manufacturer must produce and maintain production molds corresponding to each rear tip extender size at a considerable cost to the manufacturer. Consequently, while providing a plurality of sizes of rear tip extenders insures a proper fit for the implantable penile prosthesis, doing so prevents manufacturers from mass producing implantable penile prosthesis having rear tip extenders in a cost efficient manner.

A related drawback of individually molding different sized rear tip extenders is that each tip extender is of a fixed size and cannot be adjusted to accommodate discrete sizes between the pre-molded sizes. An important consideration with implantable penile prosthesis is that the size and fit of the prosthesis must closely match the patient's needs to prevent patient discomfort during use. Consequently, the

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ideal size for a particular patient is often between one of the sizes of rear tip extender, which can cause patient discomfort.

SUMMARY OF THE DISCLOSURE

The present invention is directed to an implantable penile prosthesis having an adjustable length rear tip extender adapted to change the effective length of the implantable penile prosthesis. A single rear tip extender, according to embodiments of the present invention, can be selectively set at multiple lengths according to the needs of the patient. Unlike conventional rear tip extenders that are molded in a single length and must be interchanged with a different rear tip extender of a different molded length to change the overall length of the implantable penile prosthesis, the single adjustable length rear tip extender of the present invention can be provided to reduce waste and provide considerable cost in both manufacturing and storage/disposal. Further, the adjustable length rear tip extender of the present invention allows medical personnel to set the length of the rear tip extender at the most ideal length, and at the ideal time, for the patient rather than selecting from a set of rear tip extenders having predetermined lengths.

In certain embodiments of the present invention, the adjustable length rear tip extender can include a telescoping rear tip extender. The telescoping rear tip extender can generally comprise an interface segment, at least one telescoping segment, and a conical end segment. The interface segment can include a receiving port for receiving the mounting nub at the rear of an inflatable cylinder and operably linking the telescoping rear tip extender to the inflatable cylinder. Each telescoping segment generally includes a frustoconical shape and can be affixed together in an end-to-end configuration with other like telescoping segments to change the overall length of the rear tip. The conical end segment includes a conical shape and is adapted to be affixed to a telescoping segment such that the combined conical end segment and telescoping segment comprise a generally conical shape. The interface segment is affixable to the opposite end of a telescoping segment or series of telescoping segments from the conical end segment such that the telescoping rear tip defines a generally conical shape pointing outwardly from the end of an inflatable cylinder. According to an embodiment of the present invention, the interface segment and each of the telescoping segments defines an internal lumen for receiving the segment in the series and ultimately the conical end segment. In this configuration, the interface segment, each telescoping segment and the conical end segment, each include a smaller outer diameter than the preceding segment. According to embodiments of the present invention, each segment can comprise a locking segment for locking each segment, or a group of series of segments, in the extended position by rotating the extended segment relative to the preceding segment.

According to other embodiments of the present invention, an adjustable length rear tip extender can comprise a fluted rear tip extender comprising a conical end segment, an interface segment and a plurality of conical intermediate segments. As with the telescoping rear tip extender, the interface segment of the fluted rear tip defines a receiving port for receiving the mounting nub at the rear of an inflatable cylinder and operably linking the fluted rear tip extender to the inflatable cylinder. The plurality of conical intermediate segments are arranged in an end-to-end configuration with each intermediate segment comprising a tab

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operably linking each conical end segment to the preceding conical intermediate segment. Similarly, the conical end segment further comprises a tab operably linking the conical end segment to the series of conical intermediate segments. The effective length of the fluted rear tip can be changed by cutting along a tab between a pair of conical intermediate segments, a conical intermediate segment or a conical end segment, or a conical intermediate segment and the interface segment. The conical intermediate segments comprise a conical shape such that regardless of the effective length chosen, the effective end of the fluted rear tip will have a rounded shape. According to embodiments of the present invention, the fluted rear tip comprises a plurality of frustoconical intermediate segments wherein the narrow end of each intermediate segment is affixed to the wide end of the next intermediate segment. In either embodiment of the fluted rear tip, the entire fluted rear tip can be molded as a single piece.

The above summary of the various representative embodiments of the invention is not intended to describe each illustrated embodiment or every implementation of the invention. Rather, the embodiments are chosen and described so that others skilled in the art can appreciate and understand the principles and practices of the invention. The figures in the detailed description that follow more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE FIGURES

The invention can be completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

FIG. 1 shows an implantable penile prosthesis in accordance with embodiments of the present invention.

FIG. 2 shows an inflated implantable penile prosthesis in accordance with embodiments of the present invention.

FIG. 3 shows a deflated implantable penile prosthesis in accordance with embodiments of the present invention.

FIGS. 4a-4c show a telescoping rear tip extender being in stages of telescoping extension in accordance with embodiments of the present invention.

FIG. 4d shows a schematic cross-sectional view of the telescoping rear tip extender of FIG. 4c in accordance with embodiments of the present invention.

FIG. 5 shows a fluted rear tip extender having intermediate tabs in accordance with embodiments of the present invention.

FIG. 6 shows a trimmed or shortened fluted rear tip extender of FIG. 5 in accordance with embodiments of the present invention.

FIGS. 7-8 show a fluted rear tip extender in accordance with embodiments of the present invention.

FIG. 9 shows a trimmed or shortened fluted rear tip extender of FIGS. 7-8 in accordance with embodiments of the present invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE FIGURES

Referring generally to FIGS. 1-3, an implantable penile prosthesis system 2, according to embodiments of the pres-

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ent invention, comprises one or more inflatable cylinders 4 (e.g., 2 adjacent cylinders) each operably linked to an inflating apparatus or reservoir 6 via one or more fluid conduits or connectors 8. The one or more inflatable cylinders 4 further include an inflatable portion 10 and a rear tip portion 12. The one or more inflatable cylinders 4 can include a valve 14 (e.g., one-way) switchable between a first position wherein fluid can only enter the inflatable cylinders 4 via the fluid connectors 8 and a second position wherein fluid can only leave the inflatable cylinders 4, also via the fluid connectors 8. In certain embodiments, the rear tip 12 can further include a locking mechanism or device. The inflating apparatus 6 can include a pump 18 that can be actuated to feed an inflation fluid through the one or more fluid connectors 8 and into the inflatable portion 10 of the one or more inflatable cylinders 4.

In general operation, the one or more inflatable cylinders 4 are surgically positioned within the corpus cavernosum of the penis with the inflating apparatus 6 positioned within the scrotum. The patient can actuate the pump 18 of the inflating apparatus 6 to force fluid through the fluid connector 8 into the inflatable portion 10 of the inflatable cylinder 4 causing the inflatable cylinder 4 to inflate. According to embodiments of the present invention, the valve 14 is biased into the first position so as to only permit fluid to enter the inflatable cylinder 4, wherein the valve 14 must be manually actuated to the second position by the patient to permit fluid to leave the inflatable cylinder 4 and deflate the inflatable portion 10. Actuating the valve 14 to the second position drains the inflating fluid from the inflatable cylinder 4 and returns the inflating fluid to the inflating apparatus 6.

Referring generally to FIGS. 4a-4d, the implantable penile prosthesis 2 can comprise a telescoping rear tip extender 20 affixable to the rear tip 12 of each inflatable cylinder 4. The telescoping rear tip extender 20 comprises an interface segment 22, at least one telescoping segment 24 and a generally rounded conical end segment 26. The interface segment 22 defines a receiving port 28 having a shoulder 30 for engaging a locking feature 16 of the inflatable cylinder 4. The locking feature can include a locking nub. In other embodiments, the locking feature 16 can include a snap-fit portion, detent mechanism or feature, threading portion, and the like. Each telescoping segment 24 can include a first end 32 and a second end 34, wherein the diameter of the telescoping segment 24 is greater at the first end 32 than the second end 34 so as to define a generally frustoconical shape. The conical end segment 26 defines a generally conical shape and is adapted to brace against the pelvic bone to stabilize the implantable penile prosthesis. The telescoping segments 24 are arranged in an end-to-end configuration where the smaller second end 34 of each telescoping segment 24 interfaces with the larger first end 32 of the next telescoping segment 24. The conical end segment 26 is adapted to interface with the second end 34 of the last telescoping segment 24, while the interface segment 22 is adapted to interface with the first end 34 of the first telescoping segment 24.

According to embodiments of the present invention, the telescoping segments 24 and the conical end segment 26 are adapted to collapse partially or entirely into the interface segment 22 to shorten the effective length of the rear tip extender. Similarly, the telescoping segments 24 and the conical end segment 26 are adapted to extend partially or entirely from the interface segment 22 to increase the effective length of the rear tip extender. In this configuration, the interface segment 22 defines a bore 36 for receiving the telescoping segments 24 and the conical end segment 26.

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Similarly, the telescoping segments **24** each define a bore **38** sized to receive the next telescoping segment **24**. In this configuration, the telescoping segments **24** each define a smaller maximum outer diameter than the preceding telescoping segment **24**, with the conical end segment **26** having the smallest outer diameter of any of the segments.

In embodiments of the present invention, the interface segment **22**, the telescoping segments **24** and the conical end segment **26** can each include a locking mechanism or assembly **40**. The locking assembly **40** is adapted to lock the segments in an extended position by twisting the segment relative to the preceding segment to engage the locking assembly **40**. The locking assembly **40** can comprise a threaded assembly, a locking ring, a detent mechanism, a snap-fit feature, a press-fit feature and other means of locking the segments in the extended position. The interface segment **22**, the telescoping segments **24**, and the conical end segment **26** can be provided as individual segments in a kit, wherein medical room personnel can select the appropriate number of segments to achieve the desired overall length of the telescoping rear tip extender **20**. While the telescoping extender **20** is generally depicted with three extending or distinct segments for adjusting rear tip extender lengths, embodiments can include numerous configurations, with additional (e.g., 4, 5, 6, . . .), or fewer (e.g., 2), distinct telescoping segments to define the available lengths for the extender **20**. Further, the segments **22**, **24** can be configured in various sizes. For instance, certain embodiments can provide segments 0.5 or 1.0 cm in height such that telescoping adjustment lengthens the extender **20** in 0.5 or 1.0 cm increments. Other size and increment options are obviously available as well.

Referring to FIGS. 5-6, embodiments of the implantable penile prosthesis **2** can include a fluted rear tip extender **42** affixable to the rear tip **12** of each inflatable cylinder **4**. The fluted rear tip extender **42** further comprises an interface segment **44** and a plurality of conical segments **46**. The interface segment **44** can include a receiving port **48** having a mating feature **50**, such as a shoulder, for engaging the locking feature **16** (e.g., locking nub) of the inflatable cylindrical **4** or rear tip **12**. Each of the conical segments **46** comprises a generally rounded conical tip **52** adapted to brace the rear tip extender **42** against the pelvic bone and tab **54** extending outwardly from the rear of the conical tip **52**.

The conical segments **46** are arranged in an end-to-end configuration with the tab **54** of each conical segment **46** being affixed to the conical tip **52** of the preceding conical segment **46**, with the final tab **54** of the last conical segment **46** being affixed to the interface segment **44**. In operation, a user or physician can cut across the tab **54** to shorten the length of the rear tip extender **42** and expose the conical tip **52** below or preceding the cut tab **54**. The length of each conical segment **46** from the tip **52** to end of the tab **54** can be a suitable length such as, for example, 0.5 cm such that removing each conical segment **46** from the fluted rear tip extender **42** shortens the effective length of the fluted rear tip extender **42** by 0.5 cm. For example, in certain embodiments, the overall length from the interface segment **44** to the tip **52** of an uncut or unaltered extender **42** can be from 1.0 cm to over 20.0 cm. FIG. 6 shows an embodiment of the fluted extender **42** of FIG. 5 cut or otherwise reduced in overall length to include three distinct segments, e.g., one interface segment **44** and two conical segments **46**.

As shown in FIGS. 7-9, according to an embodiment of the present invention, the fluted rear tip extender **42** can alternatively comprise frustoconical intermediate segments **58** and a conical end segment or tip **60** instead of a plurality

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of conical segments **46**. Each frustoconical segment **58** comprises a first end **62** and second end **64**, wherein the outer diameter of the frustoconical segment **58** is greater than the outer diameter at the second end **64**. As with the conical segments **46**, the frustoconical segments **58** are arranged in an end-to-end configuration. However, unlike the conical segments **46**, the second end **64** of each frustoconical segment **58** can be adapted to interface directly with the first end **62** of the next frustoconical segment **58**. As a result, the effective length of the fluted rear tip extender **42** with frustoconical intermediate segments **58** is changed by cutting between the frustoconical segments **58** rather than along the tabs **54**. In certain embodiments, the conical end segment **60** is selectively affixed (e.g., snap-fit, press-fit, etc.) to the second end **64** of the last frustoconical segment **58**, while the interface segment **44** is affixed to the first end **62** of the first frustoconical segment **58**. In other embodiments, the interface segment **44** can be selectively affixed (e.g., snap-fit, press-fit, threaded, etc.) to or in the first end **62** of the first segment **58**. FIG. 9 shows an embodiment of the fluted extender **42** of FIG. 7 cut or otherwise reduced in overall length to include six distinct segments, e.g., one interface segment **44**, four segments **58** and the tip **60**.

Various embodiments of the fluted rear tip extender **42** can be molded as a single piece from a suitable polymer material. As a result, the fluted rear tip extender **42** saves considerable manufacturing cost as only a single mold is required to produce the fluted rear tip extender **42**, while still providing the flexibility to change the effective length of the rear tip extender **42** as required.

In certain embodiments of the extenders **20**, **42**, portions or segments can include indicia or other markings to indicate various effective lengths for the extender **42**, e.g., if cut down or at that particular segment for implantation. Indicia can also be provided to indicate cut or break lines to shorten the overall length of the extenders. Further, cutting off excess length can include trimming end regions of the cut segments or tabs (e.g., tabs **54**) to provide the desired surface contour or consistency for the corresponding segment or tip.

The penile prosthesis **2**, features, devices, structures and methods detailed herein are envisioned for use with many known penile prosthesis implants and systems (e.g., for male and female), features and methods, including those disclosed in U.S. Pat. Nos. 8,052,594, 7,169,103, 6,808,489 and 5,263,981. Accordingly, the above-identified disclosures are fully incorporated herein by reference in their entirety.

Generally, a method for implanting the penile prosthesis **2** having the telescoping rear tip extender **20** into a patient's body comprises making an incision in the patient's body proximate to the patient's corpus cavernosum. The one or more inflatable cylinders **4** are then inserted into the corpus cavernosum. The telescoping rear tip extender **20** is fitted to the rear tip **12** of the inflatable cylinder **4**, e.g., snap-fit, nub elements, detents, threading, and the like. The telescoping rear tip extender **20** is extended until the conical end segment **26** abuts the patient's pelvic bone to achieve the desired length for the extender **20** and the effective overall length of the prosthesis **2** according to the individual anatomy of the patient. In other embodiments, the telescoping rear tip extender **20** is extended to the proper length prior to attachment to the inflatable cylinder **4**.

Similarly, a method for implanting the implantable penile prosthesis **2** having the fluted rear tip extender **42** also comprises making an incision in the patient's body proximate to the patient's corpus cavernosum. The one or more implantable cylinders **4** are then inserted into the corpus cavernosum. The fluted rear tip extender **42** is then cut to

shorten the extender 42 to the appropriate length in accordance with the patient's anatomical length, such that the end of the fluted rear tip extender 42 abuts against the pelvic bone while properly aligning the implantable cylinders 4 within the corpus cavernosum.

All patents, patent applications, and publications cited herein are hereby incorporated by reference in their entirety as if individually incorporated, and include those references incorporated within the identified patents, patent applications and publications.

Obviously, numerous modifications and variations of the present invention are possible in light of the teachings herein. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

What is claimed:

1. A penile prosthesis system, comprising:
at least one inflatable cylinder having a rear tip portion;
and
a fluted rear tip extender attachable to the rear tip portion of the at least one inflatable cylinder, the rear tip extender having a conical end segment, a plurality of generally frustoconical segments in serial alignment, and a base interface segment, the base interface segment configured to be attached to the rear tip portion of the at least one inflatable cylinder,
each of the plurality of generally frustoconical segments having a first flared end and a second distal end, the plurality of frustoconical segments being integrally formed and substantially the same shape such that the second distal end of one of the plurality of frustoconical segments directly interfaces with the first flared end of another of the plurality of frustoconical segments, each of the plurality of frustoconical segments having a marking indicative of an effective length of the rear tip extender,
the plurality of frustoconical segments including a first end frustoconical segment coupled to the base interface segment, one or more intermediate frustoconical segments, and a second end frustoconical segment removably coupled to the conical end segment,
wherein the fluted rear tip extender is molded as a single piece from a polymer material,
wherein the second end frustoconical segment can be removed from the fluted rear tip extender by cutting between segments, and one of the intermediate frustoconical segments can be coupled to the conical end segment to shorten the effective length of the rear tip extender.
2. The system of claim 1, further including a fluid reservoir and a pump device, wherein the fluid reservoir,

pump device, and the at least one inflatable cylinder are in fluid communication via one or more conduits.

3. The system of claim 1, wherein the plurality of generally frustoconical segments includes five or more generally frustoconical segments.

4. The system of claim 1, wherein the base interface segment includes an engagement feature to facilitate attachment of the rear tip extender to the rear tip portion of the at least one inflatable cylinder.

5. The system of claim 1, wherein the conical end segment is configured to brace against a pelvic bone.

6. A penile prosthesis system, comprising:
at least one inflatable cylinder having a rear tip portion;
and

a fluted rear tip extender attachable to the rear tip portion of the at least one inflatable cylinder, the rear tip extender having a conical end segment, a plurality of integrally formed generally tapered segments in serial alignment, substantially the same shape, and having a first flared end and a second distal end such that the second distal end of one of the plurality of tapered segments directly interfaces with the first flared end of another of the plurality of tapered segments, the rear tip extender including a base interface segment configured to be attached to the rear tip portion of the at least one inflatable cylinder, each of the plurality of tapered segments having a marking indicative of an effective length of the rear tip extender,

the plurality of tapered segments including a first end tapered segment coupled to the base interface segment, a plurality of intermediate tapered segments, and a second end tapered segment removably coupled to the conical end segment,

wherein the fluted rear tip extender is molded as a single piece from a polymer material,

wherein the second end tapered segment and one or more of the plurality of intermediate tapered segments can be removed by cutting between segments, and the second distal end of an unremoved intermediate tapered segment can be coupled to the conical end segment to shorten the effective length of the rear tip extender.

7. The system of claim 6, further including a fluid reservoir and a pump device, wherein the fluid reservoir, pump device, and the at least one inflatable cylinder are in fluid communication via one or more conduits.

8. The system of claim 6, wherein the plurality of tapered segments includes five or more generally tapered segments.

9. The system of claim 6, wherein the plurality of tapered segments are frustoconical.

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